

**REMARKS**

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-163 are in this case. Claims 86-149 are withdrawn from consideration as being drawn to a non-elected invention. Claims 57-85, 150-157 and 159-160 were rejected under 35 USC § 112 first and second paragraphs. Claims 1-5, 10-14 and 25 were rejected under 35 USC §102 as being anticipated by Amer et al. (U.S. Patent No. 4,759,956, hereinafter also referred to as Amer). Claims 150-156 were rejected under 35 USC §102 as being anticipated by Boddie et al. (J. Dairy Sci. 79, 1996, p. 1683-1688, hereinafter also referred to as Boddie). Claims 26, 35-38, 57-68, 150 and 155-157 were rejected under 35 USC §102 as being anticipated by Danner et al. (U.S. Patent No. 5,855,922, hereinafter also referred to as Danner). Claims 1-5, 9-11, 26-30, 39-40, 57-61, 65-67 and 69-70 were rejected under 35 USC §102 as being anticipated by Karagoezian et al. (U.S. Patent No. 6,592,907, hereinafter also referred to as Karagoezian). Claims 1-11, 15-37, 39-40, 44-67, 69-70, 74-85, 150-151 were rejected under 35 USC §102 as being anticipated by Green et al. (U.S. Patent No. 6,592,890, hereinafter also referred to as Green). Claims 41-43 and 71-73 were rejected under 35 USC §103 as being obvious in view of Green and Boddie.

Claims 5-12, 14, 15, 30-34, 36-41, 43, 44, 61-64, 66-71, 73-74, 152 and 154-157 have now been canceled. Claims 1, 13, 16, 20-24, 25, 26, 42, 45, 46, 51-55, 57, 72, 75, 76, 79, 80-84, 150, 153, 158, 159, 160, 162 and 163, have now been amended.

Before referring to each of the Examiner's rejections and objection, Applicant wishes to point out that the claims before the Examiner are directed to a composition-of-matter that comprises an oxidizing agent such as a chlorinated isocyanurate, being entrapped in or by a sustained-release carrier such as a silicone polymer, whereby the chlorinated isocyanurate functions as a therapeutically active agent for treating skin or mucosal membrane ailment such

as those caused by a human papilloma virus (HPV). The claims before the Examiner are further directed to pharmaceutical compositions containing same and to methods of treating skin or mucosal membranes ailments caused by HPV, which utilize an oxidizing agent such as chlorinated isocyanurate, either free or entrapped in or by a sustained-release silicone polymer carrier.

A preferred oxidizing agent, according to the teachings of the present invention, is a chlorinated isocyanurate. -Chlorinated isocyanurates, such as the commercially available trichloro(iso)cyanurate (TCIA) and sodium dichloro(iso)cyanurate (DCIA), are known to produce hypochlorous acid (HOCl) upon reaction with water. These reagents are highly active, even at very low concentrations, and are therefore widely used as oxidizing agents and particularly as water disinfectants and bleaching agents. HOCl is widely known as a source of free chlorine, a well- recognized oxidizing moiety.

However, although the use of chlorinated isocyanurates as oxidizing agents is well known, these compounds have never been used heretofore as therapeutically active agents for treating skin or mucosal membrane ailments, due to the high reactivity thereof.

In order to overcome the limitations associated with the high reactivity of widely used oxidizing agents such as chlorinated isocyanurates and thus to enable the use of such reactive anti-microbial, anti-fungal and anti-viral agents as therapeutically active agents, the present inventors have developed a novel methodology, according to which a hydrolizable oxidizing agent, which generates an active oxidizing moiety upon hydration thereof, is used. In one embodiment of the present invention, the hydrolizable oxidizing agent is entrapped in or by a polymer, which is designed so as to enable the sustained release of an active oxidizing moiety, formed upon hydration of the oxidizing agent. This methodology and embodiments thereof are described in detail in the instant application (see, for example, the description at page 34, lines 3-13). Thus, the use of highly reactive oxidizing agents as therapeutically active agents is made possible.

The design and preparation of exemplary silicone polymers that act as sustained-release carriers of the oxidizing agent is widely taught in the instant application (see, for example, the description beginning at page 24, line 5 and ending at page 28, line 6; the description beginning at page 31, line 14 and ending at page 32, line 17; the description beginning at page 34, line 3 and ending at page 34, line 18; the description beginning at page 39, line 1 and ending at page 39, line 15; the description beginning at page 41 line 4 and ending at page 41, line 17; and pages 42-45 in the Examples section. The beneficial use of such polymers, entrapping therein or thereby a chlorinated isocyanurate, in treating warts caused by HPV is widely demonstrated on pages 46-48 in the Examples section of the instant application.

As is argued in detail hereinbelow, the prior art fails to teach or suggest the use of chlorinated isocyanurates as therapeutically active agents for treating skin ailments such as those caused by HPV. The prior art further fails to teach or suggest the incorporation of such therapeutically active agents in silicone polymers, which act as sustained release carriers of the oxidizing agent.

#### ***Claim objection***

The Examiner has objected to claim 162 for reciting the word "proceeds" instead of the word "precedes".

Claim 162 has now been amended to correctly recite the word "precede", so thereby overcome the Examiner's objection.

#### ***35 U.S.C. § 112 second paragraph rejection***

The Examiner has rejected claims 159-160 under 35 USC § 112, second paragraph, as being vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 159 and 160 have now been amended.

Specifically, the Examiner has stated that in claim 159 the phrase “*polymerizing a second silicone polymer so as to obtain a second polymerized silicone polymer*” and in claim 160 the phrase “*polymerizing a silicone polymer so as to form a polymerized silicone polymer*” are not clear, in respect to the cross-linking of the polymer.

Claims 159 and 160 have now been amended so as to more clearly define the claimed subject matter. Specifically, claim 159 has now been amended to recite “[t]he method of claim 158, ... ***wherein said second polymerized silicone polymer comprises a cross-linked silicone polymer***”.

Claim 160 has now been amended to recite: “[a] method of preparing a pharmaceutical composition,... ***wherein said polymerized silicone polymer comprises a cross-linked silicone polymer***.”

Applicant therefore believes to have overcome the Examiner's rejection in this respect.

### ***35 U.S.C. § 112 first paragraph rejection***

The Examiner has rejected claims 57-85 and 150-157 under 35 USC § 112, first paragraph, as failing to enable any person skilled in the art to use the invention commensurate in scope with these claims. The Examiner's rejection is respectfully traversed. Claims 61-64, 66-71, 73-74, 152 and 154-157 have now been canceled. Claims 57, 72, 75, 76, 79, 80-84, 150 and 153 have now been amended.

Specifically, the Examiner has stated that the specification does not reasonably provide enablement for all skin or mucosal membrane ailments and has referred in detail to the eight Wand factors.

Applicant wishes to direct the Examiner's attention in this respect to the specification of the instant application (see, for example, pages 5-7 and pages 29-31), where it is recited that HOCl is a known and common source of free chlorine, and hence is typically used as an aggressive oxidizing and chlorinating agent. As such, HOCl is a known as anti-microbial, anti-fungal

and anti-viral agent, especially in water purification systems. In addition, it is recited that chlorinated isocyanurates, such as the commercially available trichloro(iso)cyanurate (TCIA) and sodium dichloro(iso)cyanurate (DCIA), are known to produce HOCl upon reaction with water. Taken together, it is clear that chlorinated isocyanurates, while being capable of producing HOCl, may exert anti-microbial, anti-fungal and anti-viral activity and are indeed utilized as such in water purification systems.

As is further discussed in the Background section of the instant application, due to the high reactivity of chlorinated isocyanurates, these oxidizing agents have never been utilized heretofore as therapeutically active agents for treating skin ailments. These limitations are overcome by the methodology taught by the present invention, and particularly, by incorporating the chlorinated isocyanurates in a silicone polymer that is designed and acts as a sustained-release carrier of the chlorinated isocyanurate and/or of the hypochlorous acid generated upon hydration thereof..

Since the anti-microbial, anti-fungal and anti-viral activities of these agents are widely recognized, it should have been obvious to a skilled artisan that by using the methodology taught the present invention, any ailment that is caused by bacteria, fungi or virus, and which is treatable by HOCl, would be treatable by compositions that comprise chlorinated isocyanurates incorporated in a silicone polymer sustained-release carrier. Applicant therefore strongly believes that by using the methodology described in the instant application, and particularly, the methods of preparing the compositions and the methods of treating skin ailments described thereby, sufficient enablement regarding how to use or make the invention in terms of the eight Wand factors is provided.

Notwithstanding the above, and in order to expedite prosecution, Applicant has chosen to limit the claimed invention, so as to more clearly define the claimed subject matter. Specifically, Applicant has chosen to limit the scope of independent claims 57 and 150 to skin or mucosal membranes ailment caused by HPV. Applicant has further chosen to limit the scope of

these claims to chlorinated isocyanurate as the oxidizing agent. Applicant has further chosen to limit the scope of claim 57 to a chlorinated isocyanurate entrapped in or by a silicone polymer.

Specifically, claim 57 has now been amended to recite: “[a] method of treating a skin or mucosal membranes ailment *caused by HPV*, the method comprising applying onto a treated region of the skin or mucosal membranes *a therapeutically effective amount of a chlorinated isocyanurate* being entrapped in or by a pharmaceutical sustained-release carrier, said carrier comprises a biocompatible *silicone* polymer.”

Claim 150 has now been amended to recite: “[a] method of treating a skin or mucosal membranes ailment *caused by HPV*, the method comprising applying onto a treated region of the skin or mucosal membranes *a therapeutically effective amount of a chlorinated isocyanurate*.”

As a result of these amendments, claims 61-64, 66-71 and 73-74, which included subject-matter that has now been excluded from the scope of independent claim 57, have now been canceled. Claims 72 and 75-83 have now been amended to depend from claim 57.

Similarly, claims 152 and 154-157 have now been canceled and claim 152 has been amended to depend from claim 150.

Ample support, enablement and working examples demonstrating the preparation and such compositions and their beneficial effect in treating warts caused by HPV are provided in pages 46-48 in the Examples section. Thus, for example, the treatment of a skin growth present for about 2 years on the hand of a 50 years old woman, the treatment of a 40 years old woman that had three different growths on her hand, for about one year, and the treatment of a 40 years old man had a growth of about 4 mm diameter, are discussed (see pages 46-48). The compositions used in treating warts caused by HPV were prepared according to the detailed description on pages 42-46.

Applicant therefore believes to have overcome the Examiner's rejection in this respect.

**35 U.S.C. § 102 (b) rejection – Amer et al.**

The Examiner has rejected claims 1-5, 10-14 and 25 under 35 USC §102(b) as being anticipated by Amer et al. (U.S. Patent No. 4,759,956). The Examiner's rejections are respectfully traversed. Claims 5, 10-12 and 14 have now been canceled. Claims 1, 13 and 25 have now been amended.

Specifically, the Examiner has stated that Amer discloses a detergent composition comprising solid particles, which comprise of oxidizing agents encapsulated with polymers, and that a wide variety of polymers which are conformable, flexible and spreadable are disclosed. Furthermore, the Examiner has stated that the solid particles disclosed in Amer are oxidizing materials, especially chlorine releasing agents, including sodium dichloroisocyanurate and more.

As is argued hereinabove, the present invention is directed to oxidizing agents such as chlorinated isocyanurates, which, by being entrapped in or by silicone polymers, can serve as efficient therapeutically active agents for treating skin ailments. The silicone polymers are designed and act as carriers for the sustained-release of the oxidizing agent and/or an oxidizing moiety (e.g., free chlorine) generated upon hydration of the oxidizing agent.

While Amer teaches the encapsulation of various oxidizing agents in polymers, for use as detergents, Amer fails to teach (i) the use of chlorinated isocyanurates and other oxidizing agents as therapeutically active agents; (ii) the entrapment of oxidizing agents such as chlorinated isocyanurates in or by silicone polymers; and (iii) the use of silicone polymers as a carrier for the sustained-release of the oxidizing moiety or agent.

In order to more clearly distinct the claimed invention from the teachings of Amer, Applicant has chosen to amend independent claim 1, to recite “[a] composition-of-matter comprising a *silicone* polymer and *a therapeutically effective amount of a chlorinated isocyanurate for treating a skin or mucosal membrane ailment caused by a human papilloma virus (HPV), said chlorinated isocyanurate* being entrapped in or by said polymer.”

Consequently, claims 5-9 and 10-15, which included subject-matter that has now been excluded from the scope of the claims, have now been canceled. Claims 13, 16 and 25 have now been amended to depend from claim 1 and/or to recite the same limitations as in amended claim 1.

Applicant strongly believes that amended independent claim 1, as well as claims 2-4, 13 and 25, which directly or indirectly depend therefrom, are not anticipated by Amer and are therefore allowable.

***35 U.S.C. § 102 (b) rejection – Boddie et al.***

The Examiner has rejected claims 150-156 under 35 USC §102 (b) as being anticipated by Boddie et al. (J. Dairy Sci. 79, 1996, p. 1683-1688). The Examiner's rejections are respectfully traversed. Claims 152 and 154-156 have now been canceled. Claims 150 and 153 have now been amended.

Specifically, the Examiner has stated that Boddie discloses a method for treating teat skin infected by microorganism, whereas the microorganism is a bacteria, such as staphylococcus, by dipping teats in the formulation containing 4% by weight sodium hypochlorite an oxidizing agent, and further discloses hypochlorous acid (as a source of free chlorine, liberated from sodium dichloroisocyanurate in water by hydrolysis), that was effective against the same bacteria

Boddie teaches a method of treating teat infection, which utilizes a chlorinated isocyanurate as an oxidizing agent that releases hypochlorous acid in water. While Boddie teaches a method of treating a teat infection, Boddie fails to teach a method of treating a skin ailment. As is well-known in the art, teat infections typically involve internal infections, which can be reflected, *inter alia*, by skin symptoms. Furthermore, the specific teat infection cited by Boddie is caused by certain bacteria. Boddie is therefore completely silent with respect to treating infections caused by other microorganisms and further fails to teach skin ailments *per se*, that is, ailments that affect the skin itself.



Contrary to Boddie, claims 150-156 are directed to the use of an oxidizing agent such as a chlorinated isocyanurate, which can release hypochlorous acid upon contacting water, in the treatment of skin ailments such as those caused by HPV. The beneficial effect of these compositions in treating skin ailments such as warts caused by HPV is widely demonstrated in the instant application (see, for example, pages 46-48 in the Examples section).

It is therefore clear that Boddie fails to teach compositions which include a chlorinated isocyanurate that can be utilized in the treatment of skin ailments in general and of skin ailments caused by HPV in particular.

Notwithstanding the above, Applicant has chosen, in order to expedite prosecution, to amend independent claim 150, so as to more clearly distinct the claimed invention from the teachings of Boddie. Specifically, claim 150 has now been amended to recite “[a] method of treating a skin or mucosal membranes ailment **caused by HPV**, the method comprising applying onto a treated region of the skin or mucosal a **chlorinated isocyanurate**”

Consequently, claims 152 and 154-156, which included subject matter that has now been excluded from the scope of amended claim 150 and/or which included limitations now added to amended claims 150, have now been canceled. Claim 153 which originally depended on claim 152 has now been amended to depend on claim 150.

Applicant strongly believes that amended independent claim 150, as well as claims 151 and 153, which directly or indirectly depend therefrom, are not anticipated by Boddie and are therefore allowable.

***35 U.S.C. § 102 (b) rejection – Danner et al.***

The Examiner has rejected claims 26, 35-38, 57-68, 150 and 155-157 under 35 USC §102 (b) as being anticipated by Danner et al. (U.S. Patent No. 5,855,922). The Examiner’s rejections are respectfully traversed. Claims 36-38, 61-64, 66-68 and 154-157 have now been canceled. Claims 26, 57, 150 and 153 have now been amended.

Specifically, the Examiner has stated that Danner discloses an antimicrobial composition comprising, as an oxidizing agent, an aqueous solution of metal chlorate, for the treatment of dermal disorders caused by viruses such as papilloma viruses, yeasts, bacteria and fungi. The Examiner has further stated that Danner teaches that the compositions may be applied to human or animal skin in conjunction with gel application medium, wherein the gels can be biocompatible polymers such as cellulose gels, polyvinylsulfonic acid, polyamide or silica based gels.

Thus, Danner, although disclosing an antimicrobial composition comprising an oxidizing agent (a metal chlorate) for the treatment of viruses, fungi and bacteria, and although further disclosing application in humans in the form of a gel, which may be a biocompatible polymer, fails to teach that: (i) an oxidizing agent such as a chlorinated isocyanurate can be used for treating skin ailments in general, and skin ailments caused by HPV in particular; and (ii) compositions which includes such as oxidizing agent being entrapped in or by a silicone polymer that is designed and acts as a sustained-release carrier thereof, as is detailed hereinabove.

Notwithstanding the above, Applicant has chosen, in order to more clearly distinct the claimed invention from the teachings of Danner, to amend independent claims 26, 57 and 150. Specifically, independent claim 26 has now been amended to recite “[a] pharmaceutical composition comprising, as an active ingredient, *a therapeutically effective amount of a chlorinated isocyanurate for treating a skin or mucosal membrane ailment caused by HPV, said chlorinated isocyanurate* being entrapped in or by a pharmaceutical sustained-release carrier, said carrier comprises a *silicone* polymer”. Independent claim 57 has now been amended to recite “[a] method of treating a skin or mucosal membranes ailment *caused by HPV*, the method comprising applying onto a treated region of the skin or mucosal membranes *a therapeutically effective amount of a chlorinated isocyanurate* being entrapped in or by a pharmaceutical sustained-release carrier, said carrier

comprises a biocompatible *silicone* polymer”. Independent claim 150 has now been amended to recite “[a] method of treating a skin or mucosal membranes ailment *caused by HPV*, the method comprising applying onto a treated region of the skin or mucosal a *chlorinated isocyanurate*”.

As a result of these amendments, claims 36-38, which included subject matter that has now been excluded from the scope of amended claim 26 and/or included limitations that have now been added to amended claim 26, have now been canceled. Claims 61-64 and 66-68, which included subject matter that has now been excluded from the scope of amended claim 57 and/or included limitations that have now been added to amended claim 57, have now been canceled. Similarly, claims 155-157, which included subject matter that has now been excluded from the scope of amended claim 150 and/or included limitations that have now been added to amended claim 150, have also been canceled.

Applicant strongly believes that amended independent claims 26, 57 and 150, as well as claims 35, 58-60 and 65, which directly or indirectly depend therefrom, are not anticipated by Danner and are therefore allowable.

### ***35 U.S.C. § 102(e) rejection – Karagoezian et al.***

The Examiner has rejected claims 1-5, 9-11, 26-30, 39-40, 57-61, 65-67 and 69-70 under 35 USC §102(e) as being anticipated by Karagoezian et al. (U.S. Patent No. 6,592,907). The Examiner’s rejections are respectfully traversed. Claims 5, 9-11, 30, 39-40, 61, 66-67 and 69-70 have now been canceled. Claims 1, 26 and 57 have now been amended.

Specifically, the Examiner has stated that Karagoezian discloses medical compositions and methods for the antimicrobial preparation to treat dermatological disorders (i.e. skin or mucous membrane) such as wounds, ulcers, psoriasis, acne and other lesions. The Examiner has further stated that Karagoezian discloses that the antimicrobial preparations comprise oxidizing agents such as hydrogen peroxide/metal chlorite, which may be formulated in a

polymeric gel or paste form, said gel or paste optionally further containing polymers which delay or control the release of the chlorite/hydrogen peroxide.

Applicant respectfully notes that the sustained-released polymers disclosed in Karagoezian (see column 10, lines 25-29) are various cellulose derivatives, such as hydroxypropyl methylcellulose (HPMC), methylcellulose (Methocel), hydroxyethylcellulose (HEC) and carboxymethylcellulose (CMC). Karagoezian therefore fails to teach the use of a silicone polymer as a sustained-release carrier of an oxidizing agent.

In addition, Karagoezian, by teaching the use of hydrogen peroxide or metal chlorite as an oxidizing agent, fails to teach the use of a chlorinated isocyanurate as an oxidizing agent that is suitable for use in the treatment of such disorders.

Applicant has therefore chosen, in order to to more clearly distinct the claimed invention from the teachings of Karagoezian to amend independent claims 1, 26 and 57. Specifically, claim 1 has now been amended to recite “[a] composition-of-matter comprising a *silicone* polymer and *a therapeutically effective amount of a chlorinated isocyanurate for treating a skin or mucosal membrane ailment caused by a human papilloma virus (HPV)*, said *chlorinated isocyanurate* being entrapped in or by said polymer”. Claim 26 has now been amended to recite “[a] pharmaceutical composition comprising, as an active ingredient *a therapeutically effective amount of a chlorinated isocyanurate* for treating a skin or mucosal membrane ailment *caused by HPV*, said *chlorinated isocyanurate* being entrapped in or by a pharmaceutical sustained-release carrier, said carrier comprises a *silicone* polymer”. Claim 57 has now been amended to recite “[a] method of treating a skin or mucosal membranes ailment *caused by HPV*, the method comprising applying onto a treated region of the skin or mucosal membranes *a therapeutically effective amount of a chlorinated isocyanurate* being entrapped in or by a pharmaceutical sustained-release carrier, said carrier comprises a biocompatible *silicone* polymer”.

As a result of these amendments, claims 5, 9-11, 30, 39-40, 61, 66-67 and 69-70, which included subject matter that has now been excluded from the scope of independent claims 1, 26 and 57 and/or which included limitations now added to independent amended claims 1, 26 and 57, have now been canceled.

Applicant strongly believes that amended independent claims 1, 26 and 57, as well as claims 2-5, 27-29, 58-60 and 65, which directly or indirectly depend therefrom, are not anticipated by Karagoezian and are therefore allowable.

***35 U.S.C. § 102(e) rejection – Green et al.***

The Examiner has rejected claims 1-11, 15-37, 39-40, 44-67, 69-70, 74-85, 150-151 under 35 USC §102(e) as being anticipated by Green et al. (U.S. Patent No. 6,592,890). The Examiner's rejections are respectfully traversed. Claims 5-11, 15, 30-34, 36-37, 39-40, 43, 44, 61-64, 66-67, 69-70, 74 and 152 have now been canceled. Claims 1, 16, 20-24, 25, 26, 42, 45, 46, 51-55, 57, 75, 76, 79, 80-84 and 150 have now been amended.

Specifically, the Examiner has stated that Green discloses a wound dressing composition having an anti-infective activity for treating skin ailments caused by microorganisms, such as bacteria, comprising a sheet of cross-linked polymeric matrix containing oxidant-generating formulation either in or on said matrix.

Applicant wishes to point out that Green discloses compositions that require the inclusion of iodine as an essential active ingredient of the composition (see for example, column 10, lines 7-24 and in the Examples). In fact, Green notes that his invention “...*circumvents the problem of trapping elemental iodine ...by the chemical method of generating iodine de novo...*” and further notes that “...*the newly formed iodine is thus able to egress and disperse throughout the wound site...*” (see, for example, the abstract). In addition, Green fails to teach chlorinated isocyanurates as the oxidizing agents

for the treatment of skin ailments in general, and for the treatment of skin ailments caused by HPV in particular.

Thus, it is clear that, contrary to the present invention, Green fails to teach (i) the use of a chlorinated isocyanurate as a therapeutically active agent; and (ii) that such a chlorinated agent, while being entrapped in a sustained-release silicone polymer, as is discussed in detail hereinabove, can be used in the treatment of skin ailments caused by HPV.

Applicant has therefore chosen, in order more clearly distinct the claimed invention from the teachings of Green, to amend independent claims 1, 26, 57 and 150. Specifically, claim 1 has now been amended to recite “[a] composition-of-matter comprising a *silicone* polymer and *a therapeutically effective amount of a chlorinated isocyanurate for treating a skin or mucosal membrane ailment caused by a human papilloma virus (HPV), said chlorinated isocyanurate* being entrapped in or by said polymer”. Claim 26 has now been amended to recite “[a] pharmaceutical composition comprising, as an active ingredient *a therapeutically effective amount of a chlorinated isocyanurate* for treating a skin or mucosal membrane ailment *caused by HPV*, said *chlorinated isocyanurate* being entrapped in or by a pharmaceutical sustained-release carrier, said carrier comprises a *silicone* polymer”. Claim 57 has now been amended to recite “[a] method of treating a skin or mucosal membranes ailment *caused by HPV*, the method comprising applying onto a treated region of the skin or mucosal membranes *a therapeutically effective amount of a chlorinated isocyanurate* being entrapped in or by a pharmaceutical sustained-release carrier, said carrier comprises a biocompatible *silicone* polymer”. Claim 150 has now been amended to recite “[a] method of treating a skin or mucosal membranes ailment *caused by HPV*, the method comprising applying onto a treated region of the skin or mucosal a *chlorinated isocyanurate*”.

As a result of these amendments, claims 5-11 and 15, which included subject matter that has now been excluded from the scope of amended claim 1

and/or included limitations that have now been added to amended claim 1, have now been canceled. Claims 30-34, 36-37, 39-40, 43 and 44, which included subject matter that has now been excluded from the scope of amended claim 26 and/or included limitations that have now been added to amended claim 26, have now been canceled. Claims 61-64, 66-67, 69-70 and 74, which included subject matter that has now been excluded from the scope of amended claim 57 and/or included limitations that have now been added to amended claim 57, have now been canceled. Similarly, claim 152, which included subject matter that has now been excluded from the scope of amended claim 150 and/or included limitations that have now been added to amended claim 150, has now been canceled.

Applicant strongly believes that amended independent claims 1, 26, 57 and 150, as well as claims 16, 20-24, 25, 42, 45, 46, 51-55, 75, 76, 79 and 80-84, which directly or indirectly depend therefrom, are not anticipated by Green and are therefore allowable.

***35 U.S.C. § 103 rejection - Green et al. in view of Boddie et al.***

The Examiner has rejected claims 41-43 and 71-73 under 35 USC §103 as being unpatentable over Green et al. in view of Boddie et al. The Examiner's rejections are respectfully traversed. Claims 41, 43, 71 and 73 have now been canceled. Claims 42 and 72 have now been amended.

Specifically, the Examiner has stated that it would have been obvious to a person skilled in the art at the time of invention to use an oxidizing agent comprising a chlorinated isocyanurate, as disclosed in Boddie, in the wound dressing composition disclosed by Green.

Following the arguments presented hereinabove in Re:Boddie and in Re:Green, Applicant respectfully wishes to point out that the usage of the chlorinated isocyanurates is disclosed in Boddie only for the treatment of internal infections and not for the treatment of "skin ailments". Furthermore, chlorinated isocyanurates are known from the field of water disinfection and

purification, but have never been disclosed for the treatment of skin ailments in general, and for the treatment of HPV in particular. Thus, a person skilled in the art would have no motivation to apply the chlorinated isocyanurates for the treatment of skin ailments, either via the Green wound dressing, or in any other way.

Applicant has chosen, in order to more clearly distinct the claimed invention from the teachings of Green and Boddie, to amend independent claims 26 and 57, so as to recite a chlorinated isocyanurate as an oxidizing agent, which is incorporated in the polymer in a therapeutically effective amount for treating a skin or mucosal membrane ailment caused by HPV. Neither Green nor Boddie teaches or merely suggests the use of a chlorinated isocyanurate for treating such skin ailments.

As a result of these amendments, claims 41 and 43, which included subject matter that has now been excluded from the scope of amended claim 26 and/or included limitations that have now been added to amended claim 26, have now been canceled. Similarly, claims 71 and 73, which included subject matter that has now been excluded from the scope of amended claim 57 and/or included limitations that have now been added to amended claim 57, have now been canceled.

Applicant strongly believes that amended independent claims 26 and 57, as well as claims 42 and 72, which directly or indirectly depend therefrom, are not rendered obvious by Green in view Boddie, and are therefore allowable. Claims 5-12, 14, 15, 30-34, 36-41, 43, 44, 61-64, 66-71, 73-74, 152 and 154-157 have now been canceled. Claims 1, 13, 16, 20-24, 25, 26, 42, 45, 46, 51-55, 57, 72, 75, 76, 79, 80-84, 150, 153, 159, 160, 162 and 163, have now been amended.

#### ***Other amendments***

While reviewing the instant application Applicant has noticed some typographical errors, which have now been amended. Specifically, Applicant



has noticed that in claims 158, 160 and 163, the word "ailment" was misspelled. Claims 158, 160 and 163 have therefore been amended so as to recite "ailment" instead of "aliment".

In view of the above amendments and remarks it is respectfully submitted that amended claim 1, claims 2-4, amended claims 13 and 16, claims 17-19, amended claims 20-26, claims 27-29 and 35, amended claims 42, 45 and 46, claims 47-50, amended claims 51-55, claims 56, amended claim 57, claims 58-60 and 65, amended claims 72, 75 and 76, claims 77 and 78, amended claims 79-84, amended claim 150, claims 151, amended claims 153, amended claims 158-160, claim 161 and amended claims 162 and 163 are now in condition for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

*Martin D. Moynihan*  
Martin Moynihan,  
Registration No. 40,338

Date: August 18, 2005

***Encl.:***

Extension of Time